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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,033	07/11/2003	Yaron Keidar	50572/AW/W112	4112

23363 7590 03/04/2010
CHRISTIE, PARKER & HALE, LLP
PO BOX 7068
PASADENA, CA 91109-7068

EXAMINER	
COLELLO, ERIN L	
ART UNIT	PAPER NUMBER
3734	
MAIL DATE	DELIVERY MODE
03/04/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/618,033	KEIDAR, YARON	
	Examiner	Art Unit	
	ERIN COLELLO	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 14, 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,4,7,9-17,19 and 23-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-4, 7, 9-17, 19 and 23-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed on January 14, 2010. Claims 1, 8 and 18 have been cancelled without prejudice. Claims 3-4, 7, 9-17, 23-24 and new claims 25-26 will be prosecuted on the merits.

Applicant's arguments with respect to claim 3-4, 7, 9-17, 23-24 have been considered but are moot in view of the new ground of rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 3-4, 7, 14-17, 19 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by **Bonutti (US 5,888,196)**.

Regarding claim 25, Bonutti discloses a device comprising: an elongated, generally flexible tubular body (Ref 14); and a dilating tip (Ref 60) slidably mounted on a distal end of the tubular body (Ref 60, 14; wherein the distal end of the dilating tip slides relative to the distal end of the tubular body) and comprising: a segmented surface comprising a plurality of segments having proximal and distal ends (Ref 60, 62; Figures 9 and 10 see below), wherein the plurality of segments is configured to move between a closed configuration in which the segments combine to form the segmented surface (Ref 62, Figure 9 see below) and an open configuration in which the segments separate

from one another (Ref 62, Figure 10 see below); a plurality of generally rigid tube segments (Ref 62; Figures 9 and 10 see below), each tube segment extending distally from a segment of the segmented surface (Ref 62; Figures 9 and 10 see below), and wherein, when the plurality of segments is in the closed configuration, the plurality of tube segments combine to form a generally rigid tube (Ref 62; Figures 9 see below; wherein the plurality of tube segments form a portion of the generally rigid tube) having a sharp distal end configured to puncture tissue (Ref 142; wherein the generally rigid tube has a sharp distal end); and a ring (Figures 9 and 10 see below) slidably mounted to the tubular body (Figures 9 and 10 see below; wherein the ring slides relative to the distal end of the tubular body), wherein the distal ends of the segments of the segmented surface are hingedly attached to the ring (Ref 62; Figure 10 see below; wherein the distal ends of the tube segments are hingedly attached to the ring); wherein proximal movement of the ring relative to the tubular body exerts a force on the segmented surface to thereby open the segmented surface (Figures 9 and 10 see below; wherein (Ref 16) and (Ref 144) move relative to each other. Therefore when (Ref 16) is held, (Ref 144) can be rotated causing (Ref 144) to move proximally which triggers the ring to move proximally collapsing the dilating tip of the tubular body to thereby force open the segmented surface).

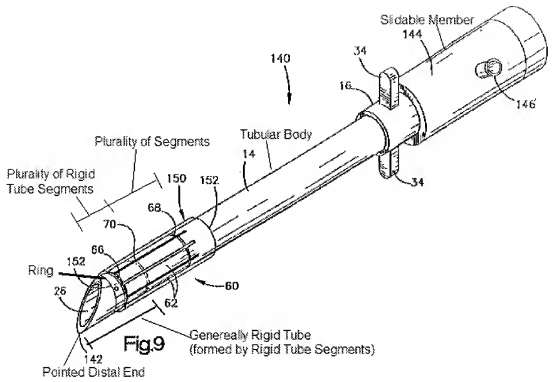
Slidable Member
144
140
34
16
146
Plurality of Segments
Tubular Body
14
Plurality of Rigid
Tube Segments
150
152
34
68
70
66
Ring
152
60
26
62
Genereally Rigid Tube
(formed by Rigid Tube Segments)
142
Pointed Distal End

Fig.9

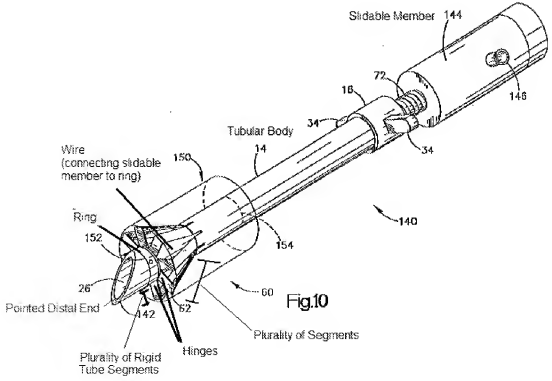
Slidable Member
144
72
16
146
Tubular Body
34
34
Wire
(connecting slidable
member to ring)
150
14
140
Ring
152
154
26
60
Pointed Distal End
142
62
Plurality of Segments
Hinges
Plurality of Rigid
Tube Segments

Fig.10

Regarding claim 26, Bonutti discloses a device comprising: an elongated, generally flexible tubular body (Ref 14); and a dilating tip (Ref 60) slidably mounted on a distal end of the tubular body (Ref 60, 14; wherein the distal end of the dilating tip slides relative to the distal end of the tubular body) and comprising: a ring mounted in surrounding relation to the distal end of the tubular body (Figures 9 and 10 see above); a segmented surface comprising three or more segments (Ref 60, 62), each segment being hingedly attached to the ring (Ref 62; Figure 10 see above), wherein the three or more segments are configured to move between a closed configuration in which the segments combine to form the segmented surface (Ref 62; Figure 9 see above) and an open configuration in which the separate from one another (Ref 62; Figure 10 see above); and three or more generally rigid tube segments (Ref 62; Figures 9 and 10 see above), each tube segment extending distally from one of the three or more segments of the segmented surface (Ref 62), wherein when the three or more segments are in the closed configuration, the three or more generally rigid tube segments combine to form a generally rigid tube (Ref 62; Figure 9 see above; wherein the plurality of tube segments form a portion of the generally rigid tube) having a sharp distal end configured to puncture tissue (Ref 142; wherein the generally rigid tube has a sharp distal end); a slidable member (Ref 144; wherein 144 slides relative to the tubular member) connected to the ring of the dilating tip (Ref 144; Figure 10 see above; wherein the slidable member is connected to the ring by means of the retractor body), wherein proximal movement of the slidable member relative to the tubular body exerts a force on the segmented surface and the generally rigid tube to thereby open the segmented

surface and the generally rigid tube (Figures 9 and 10 see above; wherein (Ref 16) and slidable member (Ref 144) move relative to each other. Therefore when (Ref 16) is held, the slidable member (Ref 144) can be rotated causing the slidable member (Ref 144) to move proximally which triggers the ring to move proximally collapsing the dilating tip of the tubular body to thereby force open the segmented surface).

Regarding claims 3 and 4, Bonutti discloses that the segmented surface comprises two or more segments (Ref 62).

Regarding claim 7, Bonutti discloses that the dilating tip is generally funnel-shaped (Figure 10, Ref 60).

Regarding claim 14, Bonutti discloses a wire (Figure 10 see above; wherein the retractor body is a long pliable metallic rod and therefore is being interpreted as a wire) extending proximally from the dilating tip to near the proximal end of the tubular body (Figure 10; wherein the wire connects the ring to (Ref 144; wherein 144 is near the proximal end of the tubular body) to effect proximal movement of the dilating tip relative to the tubular body (Figures 9 and 10 see above; wherein (Ref 16) and (Ref 144) move relative to each other. Therefore when (Ref 16) is held, (Ref 144) can be rotated causing (Ref 144) and the wire (Figure 10 see above; wherein the retractor body is a wire) to move proximally which triggers the ring to move proximally collapsing the dilating tip of the tubular body to thereby force open the segmented surface).

Regarding claim 15, Bonutti discloses a slidable member on the proximal end of the tubular body (Ref 144; wherein 144 is near the proximal end of the tubular body), the slidable member being connected to the wire (Ref 144; Figure 10 see above;

wherein the wire connects the slidable member (144) to the ring) so that proximal movement of the slidable member pulls the wire and causes proximal movement of the dilating tip relative to the tubular body (Figures 9 and 10 see above; wherein (Ref 16) and (Ref 144) move relative to each other. Therefore when (Ref 16) is held, (Ref 144) can be rotated causing (Ref 144) and the wire (Figure 10 see above; wherein the retractor body is a wire) to move proximally which triggers the ring to move proximally collapsing the dilating tip of the tubular body to thereby force open the segmented surface).

Regarding claims16 and 23, Bonutti discloses a latch for maintaining the position of the slidable member relative to the tubular body when the dilating tip is in the open arrangement configuration (Ref 22, 72; wherein the threads on the retractor body grab and hold onto the tubular body in order to maintain the position of the slidable member (144) relative to the tubular body (14)).

Regarding claims 17 and 24, Bonutti discloses a pressure valve at or near the proximal end of the tubular body (Ref 146; wherein valve 146 is used to increase the pressure in the inflatable member and can be interpreted as a pressure valve).

Regarding claim 19, Bonutti discloses that the slidable member (Ref 144; wherein 144 slides relative to the tubular member) is connected to the ring of the dilating tip by a wire having a distal end attached to the ring of the dilating tip and a proximal end attached to the slidable member (Ref 144; Figure 10 see above; wherein the retractor body is a long pliable metallic rod and therefore is being interpreted as a wire and connects the slidable member (144) to the ring of the dilating tip); wherein proximal

movement of the slidable member pulls the wire and causes proximal movement of the dilating tip relative to the tubular body (Figures 9 and 10 see above; wherein (Ref 16) and the slidable member (Ref 144) move relative to each other. Therefore when (Ref 16) is held, slidable member (Ref 144) can be rotated causing the slidable member (Ref 144) and the wire (Figure 10 see above; wherein the retractor body is a wire) to move proximally which triggers the ring to move proximally collapsing the dilating tip of the tubular body to thereby force open the segmented surface).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Bonutti (US 5,888,196)**.

Regarding claims 9-12, Bonutti discloses all of the claimed limitations above but fails to explicitly disclose that the generally rigid tube of the dilating tip has a length ranging from about 3 mm to about 5 mm or an outer diameter ranging from about 0.7 mm to about 0.8 mm.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the length of the rigid tube to be within the range from 3mm to about 5mm and the outer diameter of the rigid tube to range from about 0.7mm to about 0.8mm, since it has been held that where the general conditions of a

claim are disclosed in the prior art, discovering an optimum or working ranges involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)

Regarding claim 13, Bonutti discloses that the dilating tip can comprise a variety of materials including metals but fails to explicitly disclose that the dilating tip comprises nitinol.

However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the dilating tip comprise nitinol, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

5. Applicant's arguments with respect to claims 3-4, 7, 9-17, 23-24 have been considered but are moot in view of the new ground of rejection.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIN COLELLO whose telephone number is (571)270-3212. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. C./
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734